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UNITED STATES DEPARTMENT OF COMMERCE
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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

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Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,439,670, was filed on October 11, 1996, under 35 U.S.C. § 156. The term of U.S. Patent No. 5,439,670 subsequent to July 6, 2010 has been disclaimed.

The assistance of your Office is requested in confirming that the product identified in the application, PROVENTIL® HFA (albuterol sulfate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent may not be eligible for extension of the patent term under 35 U.S.C. § 156 since the active ingredient, albuterol sulfate, of PROVENTIL® HFA appears to have been previously approved for commercial marketing or use. Note numbered paragraph 4 and Exhibit B of the Application for Patent Term Extension. As shown in Exhibit B, a page from the Orange Book, albuterol sulfate was approved on September 25, 1995 for use in a syrup and on September 26, 1995 for use in a solution.

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.

A handwritten signature in dark ink, appearing to read "H. Bernstein", written over a horizontal line.

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Ted K. Ringsred
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